

Speak up & be heard

CONSUMER REGISTER lists summaries of major consumer proposals before Federal agencies. If you wish to submit written comments, include your name & address, state the name & *Federal Register* citation of the proposal on which you are commenting and explain your views briefly & clearly.

Social Security

As of April 16, a number of changes were made in regulations under the Social Security Act.

These include the following, according to Social Security Administration:

- Deductions will be made from disabled widows' or widowers' benefits if they refuse, without good cause, to accept vocational rehabilitation services. "Good cause" would exist, for example, if a beneficiary refuses rehabilitation services because his church teaches members to rely only on prayer or spiritual efforts for treating a physical or mental disability.

- Benefits paid to disabled widows & widowers will not be reduced because of excess earnings.

- Penalties will not be imposed for beneficiary's failure to report earnings promptly until a determination has been made about whether there is a valid reason for the delay in reporting. If a valid reason exists, no penalty deduction will be imposed.

- Where a valid reason for delay exists, a beneficiary may request & be granted an extension up to 3 months for filing the required report on earnings.

- A decision on an extension of time to file an earnings report is not subject to administrative review.

Details—*Federal Register*: April 16, page 9428.

Prescription drugs

Food & Drug Administration withdrew its approval for a number of prescription drugs as of April 25. All are cortisone-like preparations with an added ingredient to reduce stomach irritation.

The drugs no longer available for new or renewed prescriptions are

- Co-Deltra Tablets made by Merck Sharp & Dohme;
- Cordex Improved Tablets, Cordex-Forte Improved Tablets, Cordex Tablets, Cordex-Forte Tablets, Cordex (buffered) Tablets & Cordex-Forte (buffered) Tablets made by Upjohn Co.;

- Medaprin Tablets & Medadent Tablets made by Upjohn Co.;

- Delenar Tablets made by Schering Corp.;
- Dronactin Tablets made by Merck Sharp & Dohme;
- Salcort Tablets made by Beecham-Massengill Pharmaceuticals.

Withdrawal of approval followed an FDA finding that there is lack of substantial evidence that the drugs will have the effects they purport to have when used as directed in the products' labeling.

The withdrawal order also applies to all identical, related or similar products that have not been approved by FDA. Consumers wishing to know whether a specific product is covered by this notice may write to Bureau of

Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

Details—*Federal Register*: April 25, page 10169.

Drug approvals

Food & Drug Administration has proposed to withdraw its approval for the following prescription drugs:

- Dimetapp Extentabs, a drug which is an antihistamine product in the form of an extended action (or sustained release) tablet, made by A. H. Robins & Co. Inc.;

- Histadyl Solution, a drug in liquid form taken for relief of allergies, made by Eli Lilly;

- Prozine Capsules, a drug given as a tranquilizer, made by Wyeth Laboratories.

All 3 drugs were classified as "possibly effective" when they were evaluated in a 1967-69 drug efficacy study by the National Academy of Sciences-National Research Council.

Since manufacturers of these drugs have not submitted proof of the drugs' effectiveness, as requested by FDA, the agency has said it plans to withdraw its approval of them unless the company responsible for each drug submits before May 25 a written request for a hearing to show why approval should not be withdrawn.

FDA's withdrawal proposals also affect all products that are identical, related or similar to each of these 3 drugs & that have not received approval from FDA.

Consumers wishing to know whether a specific product is covered by this notice may write to Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

Details—*Federal Register*: April 25, pages 10168, 10169, 10170.

Seatbelts

May 23 is deadline for comments to National Highway Traffic Safety Administration on several proposals to amend standards for seatbelt requirements on cars to be manufactured between Aug. 15, 1973, & Aug. 15, 1975.

Due for amendment is Motor Vehicle Safety Standard No. 208.

One proposed amendment would delete Standard No. 208's "injury criteria" requirement for seatbelts. This requirement stated that belts in the front seats must be capable of meeting the injury criteria of the standard in a 30-mile-per-hour barrier test crash with dummies equipped with certain test instruments. The move to delete this request is the result of a decision by U.S. Court of Appeals for the 6th Circuit, which ruled that injury criteria could not be met consistently in tests &, thus, were invalid.

With deletion of these criteria, other safety require-

ments for seatbelts—those specified in Motor Vehicle Safety Standard No. 209—would automatically become applicable. (These latter requirements are based on 3 "strength criteria": the strength of the belt itself, the anchorage & the buckles.)

Another proposed amendment deals with Standard No. 208's requirement regarding seatbelt interlock systems. The original requirement was for an interlock system involving electronic hookups between the seatbelt lock & the car ignition; such a hookup would prevent the car from starting unless the belts had been fastened.

The proposed amendment would permit use of an alternative seatbelt interlock system that would depend on electronic hookup between the seatbelt lock & the transmission rather than between the lock & the ignition. (This would for instance allow the driver or the front-seat passenger to warm up the car or play the radio without wearing a seatbelt.)

Also proposed is the deletion of the interlock-system requirement for the front center seat. However, the warning system requirement for this center seat (combination of a buzzer & a visible light) would remain in force.

Details—*Federal Register*: April 20, page 9830. Send comments to Docket Section, National Highway Traffic Safety Administration, Washington, DC 20590. Refer to Docket No. 69.

Toys

June 15 is deadline for comments on a Food & Drug Administration proposed regulation to require that all children's toys & other articles bear certain markings & that only articles of identical construction, composition & dimensions bear identical markings.

The proposal would provide accurate & speedy identification of all toys or other articles intended for use by children. Such identification is considered necessary to speed the removal from stores & homes of toys that have been banned because they are classified as hazards.

Removal of banned toys is frequently hampered because stores often have different versions of the same article. Without identifying marks, these versions may seem indistinguishable from one another.

The proposed regulation would require that the toy itself or a tag or the retail container bear the following information; name & address of the manufacturer; a model number, stock number or identifying symbol or code.

Details—*Federal Register*: April 16, page 9436. Send comments to Hearing Clerk, Food & Drug Administration, Health Education, & Welfare Dept., 5600 Fishers Lane Rockville, MD. 20852.

Tomatoes

June 30 is deadline for comments on Agriculture Dept.'s proposal to establish a new grade size schedule for tomatoes.

The revised schedule, based on industry recommendations, is to reflect new methods of sizing & marketing. The proposed schedule would describe tomato sizes in 6 gradations with the following designations: extra small, small, large, extra large, maximum large. Minimum & maximum sizes are specified for all 6 designations.

These size designations have been developed for voluntary use by packers & wholesalers. The revised schedule would supplant a previous schedule in which the designated sizes overlapped from group to group, allowing packers to put more than one size in a container when packing tomatoes loose in bulk. The proposed schedule would provide consumers with tomatoes more nearly the same size within each grade & price range.

Also, the proposed schedule would clarify Agriculture's definition of "mature" tomatoes by requiring that tomatoes be developed enough to insure proper ripening.

Details—*Federal Register*: April 24, page 10106. Send comments to Hearing Clerk, Agriculture Dept., Washington, DC 20250.

Child resistant packaging

By April 16, 1974, Food & Drug Administration will require all prescription drugs in oral dosage form to be packaged in child resistant safety containers that cannot easily be opened by young children.

Standards for child-resistant packaging were established under the Poison Prevention Packaging Act of 1970. These standards require that 85% of a test group of 200 children (ages 41 months to 52 months) be unable to open the container in a 5-minute period & that 80% fail in another 5-minute period after being shown how to open it; 90% of a test group of 100 adults must be able to open & close the container.

The proposal concerning safety packaging for such prescription drugs was published in the *Federal Register*, April 27, 1972. At that time, FDA requested comments on the proposal. Of the 30 comments received, 13 favored the standards as proposed.

In adopting the proposal, FDA excluded from the safety packaging order those nitroglycerin preparations for oral use by patients who must be able to open the container quickly in times of stress.

While April 16, 1974, is the date when prescription-drug containers must comply with the regulation, FDA expects pharmacists will begin to use child-resistant containers as soon as they become available.

Oral prescription drugs are the 10th product for which regulations have been issued under the Poison Prevention Packaging Act. The other categories are aspirin & all aspirin products; liquid furniture polishes containing 10% or more petroleum distillates; preparations containing more than 5% methyl salicylate (wintergreen oil); controlled abuse drugs; lye preparations containing sodium or potassium hydroxide; turpentine; methyl alcohol; illuminating & kindling preparations; sulfuric acid.

Details—*Federal Register*: April 16, page 9431.

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